I. Restriction

The Examiner restricted the claims in the above-referenced application as follows:

Group I: Claims 1-21, 27, 28, 37, and 38, drawn to a tissue sealant composition, comprising a crosslinking agent, and a synthetic collagen or a synthetic gelatin, in a dry state, wherein, in the dry state, the crosslinking agent does not react with the synthetic collagen or with the synthetic gelatin, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin, thereby forming a tissue sealant composition.

Group II: Claims 17, 22-26 and 29-36, drawn to a tissue sealant composition, comprising a crosslinking agent, and a synthetic collagen or a synthetic gelatin, in a dry state, wherein, in the dry state, the crosslinking agent does not react with the synthetic collagen or with the synthetic gelatin, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin, thereby forming a tissue sealant composition further comprising a matrix scaffold; wherein the matrix comprises a type of collagen, wherein the matrix comprises a reservoir containing an aqueous solution.

Group II: Claims 39-40, drawn to a method of producing a tissue sealant, the method comprising: drying a crosslinking agent, and a synthetic collagen or a synthetic gelatin, under conditions in which the crosslinking agent, when contacted with the synthetic collagen or the synthetic gelatin under conditions other than an environment comprising about a physiological pH, does not react with the synthetic collagen or the synthetic gelatin, thereby producing tissue sealant components in a dry state; and contacting tissue sealant components with an environment comprising about a physiological pH, whereby the crosslinker reacts with the synthetic collagen or with the synthetic gelatin, thereby producing a tissue sealant.

Group III: Claims 41-49, drawn to a method of producing a tissue sealant, the method comprising: mixing a [polymeric crosslinker] and a synthetic collagen or a synthetic gelatin, under conditions in which the polymeric crosslinker does not react with the synthetic collagen or the synthetic gelatin, thereby producing a tissue sealant component mixture; and drying the tissue sealant component mixture under said conditions, thereby producing a tissue sealant in a dry state.

Group IV: Claims 50-54, drawn to a method of sealing a wound, comprising contacting the wound with the tissue sealant composition comprising a crosslinking agent, and a synthetic collagen or a synthetic gelatin, in a dry state, wherein, in the dry state, the crosslinking agent does not react with the synthetic collagen or the synthetic gelatin, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin, thereby forming a tissue sealant composition.

Group V: Claims 55-54, drawn to a kit, comprising at least one crosslinking agent, and at least one of a synthetic collagen component or a synthetic gelatin component, wherein, upon contact in a dry state, the polymeric crosslinking agent does not react with the synthetic collagen component or with the synthetic gelatin component, and wherein, upon contact with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen component or the synthetic gelatin component to form a tissue sealant composition.

Applicants note that, at page 2 of the Restriction Requirement, the Examiner provided two Group II claim listings, corresponding to claims 17, 22-26, and 29-36, and to claims 39-40, respectively. Applicants believe the Examiner intended to state that the second Group II, drawn to claims 39-40, be listed as Group III, and, correspondingly, to state that Group IV be drawn to claims 41-49, Group V be drawn to claims 50-54, and Group VI be drawn to claims 55-56. If this is incorrect, Applicants respectfully request notice and an opportunity to respond

Additionally, Applicants note that, at page 3 of the Restriction Requirement, the Examiner listed the claims of Group V as claims 55-54. Applicants believe the Examiner intended to state that Group V (now Group VI) be drawn to claims 55-56, as claim 56 depends from claim 55. If this is incorrect, Applicants respectfully request notice and an opportunity to respond.

Accordingly, below is a re-written listing of the groups of inventions associated with the application which Applicants believe the Examiner intended to state in the instant Restriction Requirement. If this is incorrect, Applicants respectfully request notice and an opportunity to respond.

Group I: Claims 1-21, 27, 28, 37, and 38.
Group II: Claims 17, 22-26, and 29-36.
Group III: Claims 39-40.
Group IV: Claims 41-49.
Group V: Claims 50-54.
Group VI: Claims 55-56.

In view of the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the requirement for restriction between Group I (claims 1-21, 27, 28, 37, and 38), Group II (claims 17, 22-26, and 29-36), Group III (claims 39-40), Group IV (claims 41-49), Group V (claims 50-54), and Group VI (claims 55-56). The Examiner stated that the "technical feature linking Groups I-V appears to be that they all relate to a tissue sealant composition comprising collagen" and that Green et al. (United States Patent No. 6,267,957) "discloses a tissue sealant composition comprising collagen..." and "[t]herefore the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art." (Restriction Requirement, page 3.) Applicants respectfully disagree with the Examiner's characterization of the special technical feature linking the inventions of the present application, and set forth below a discussion of the special technical feature which links the inventions of the present application

Applicants submit that unity of invention exists under PCT Rule 13.2 when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. (PCT Rule 13.2.)

In the present application, the invention corresponding to Groups I -VI (claims 1-56) are drwan to tissue sealant compositions comprising a crosslinking agent, a synthetic collagen or a synthetic gelatin; methods of producing a tissue sealant comprising a crosslinking agent, a synthetic collagen or a synthetic gelatin; methods of sealing a wound using a tissue sealant comprising a crosslinking agent, a synthetic collagen or a synthetic gelatin; and kits comprising a crosslinking agent, a synthetic collagen or a synthetic gelatin. The "special technical feature" linking the inventions corresponding to Groups I-VI (claims 1-56) is that the crosslinking agent of the tissue sealant composition does not react with the synthetic collagen or with the synthetic gelatin, but, wherein, upon contact of the tissue sealant composition with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin. This "special technical feature" is recited in each claim of each invention corresponding to Groups I-VI (claims 1-56) of the present application, and defines a contribution which each of the claimed inventions (i.e., Groups I-VI), considered as a whole, makes over the prior art. Accordingly, Applicants submit that unity of invention exists for the inventions corresponding to Groups I-VI (claims 1-56), as these inventions are linked by the same "special technical feature" as to form a single inventive concept.

Therefore, Applicants respectfully request reconsideration and withdrawal of the restriction requirement as it applies to the inventions corresponding to Groups I-VI (claims 1-56).

If the Examiner is not persuaded by the above statements to withdraw the restriction requirement between the inventions corresponding to Groups I-VI (claims 1-56), and in order to comply with the provisions of 37 C.F.R. 1.499, Applicants hereby provisionally elect, with traverse, the invention corresponding to the claims of Group I, claims 1-21, 27, 28, 37, and 38. Applicants reserve without prejudice the right to pursue any non-elected subject matter in continuing applications.

The Examiner further stated that the application contains claims directed to more than one species of the generic invention, and that "Applicant is required...to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable." (Restriction Requirement, page 4.) In particular, the Examiner indicated that a selection must be made according to the following.

First, the Examiner requested that, for claims 1-9, an election of a species be made from synthetic collagen and synthetic gelatin. In response, Applicants elect synthetic gelatin. Applicants submit that claims 1, 6-19, 21, 27, 28, 37, and 38 of Group I read on this elected species at least in part. If the Examiner withdraws the restriction requirement as it applies to the inventions of Groups I-VI (claims 1-56), as requested above, Applications submit that claims 17, 22-26, and 29-36 of Group II, claims 39-40 of Group III, claims 41-49 of Group IV, claims 50-54 of Group V, and claims 55-56 of Group VI read on this elected species at least in part.

Second, the Examiner requested that, depending on the election above, for claims 3 and 8, an election of a species be made from type I collagen and type III collagen. In the election above, Applicants elected synthetic gelatin. As claim 3 recites synthetic collagen, this election is moot as to this claim, and Applications respectfully request withdrawal of this election at this time. For claim 8, Applicants elect type III collagen. Applicants submit that claims 1, 6-19, 21, 27, 28, 37, and 38 of Group I read on this elected species at least in part. If the Examiner withdraws the restriction requirement as it applies to the inventions of Groups I-VI (claims 1-56), as requested above, Applications submit that claims 17, 22-26, and 29-36 of Group II, claims 39-40 of Group III, claims 41-49 of Group IV, claims 50-54 of Group V, and claims 55-56 of Group VI read on this elected species at least in part.

Third, the Examiner requested that, for claims 10-15, an election of a species be made from electrophilically activated (EA) poly(ethylene glycol) (PEG); an EA PEG derivative; PEG-succinimidyl propionate, PEG-succinimidyl butanoate, or PEG-succinimidyl glutarate. In response, Applicants elect PEG-succinimidyl propionate. Applicants submit that claims 1-21, 27, 28, 37, and 38 of Group I read on this elected species at least in part. If the Examiner withdraws the restriction requirement as it applies to the inventions of Groups I-VI (claims 1-56), as requested above, Applicants submit that claims 17, 22-26, 29-36 of Group II, claims 39-40 of Group III, claims 41-49 of Group IV, claims 50-54 of Group V, and claims 55-56 of Group VI read on this elected species at least in part.

Fourth, the Examiner requested that for claims 22-27, an election of a species be made from recombinant human type III collagen, synthetic collagen, synthetic gelatin, collagen type I, collagen type II. Applicants note that, at page 5 in the Restriction Requirement, the Examiner stated that, for claims 22-27, Applicants must select from "...collagen type II." Applicants point out that "collagen type II" is not specifically recited in any of the pending claims, and believe the Examiner intended to state "...collagen type III" rather than "...collagen type II" as one of the species for which an election is required. If this is incorrect, Applicants respectfully request notice and an opportunity to respond. Additionally, Applicants note that, at page 5 of the Restriction Requirement, the Examiner indicated that species must be selected (from recombinant human type III collagen, synthetic collagen, synthetic gelatin, collagen type I, collagen type II) for claims 22-"27." Applicants believe the Examiner intended to state that for this election, a species must be selected for claims 22-"26." If this is incorrect, Applicants respectfully request notice and an opportunity to respond. In response to this election requirement, Applicants elect type III collagen. Applicants submit that claims 17, 23-26, and 29-36 of Group II read on this elected species at least in part.

The Examiner is respectfully reminded that, pursuant to M.P.E.P 803.2, upon a finding that any one of the elected species is allowable, the Office is to extend the search.

The Commissioner is hereby authorized to charge any necessary fees or credit any overpayment to Deposit Account No. 50-0811, referencing Docket No. FP0302 US.

Please call Applicants' representative at 415-978-1744 with any questions regarding the present communication or the above-identified application.

Respectfully submitted,

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By: _____
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